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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,810	09/25/2003	Hiroatsu Toi	H04-3826/KK	5448

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,810	TOI ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks dated 03/29/2006 have been acknowledged by the Examiner.

Election/Restrictions

2. Newly submitted claims 12-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 1-11 are drawn to a microplate liquid handling system, and claims 12-14 are drawn to a liquid handling method, the two inventions being related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used with different methods, for example, for dispensing fluids into one microplate by moving the dispensing unit in one direction, and into a following microplate – by moving in another direction. The method can be practiced by hand.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-14 are withdrawn from consideration

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as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the 07/13/2005 Office Action.

4. Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakano in view of any of Overbeck et al. (US 6722395), Lebl et al. (US 20020028159) or Stylli et al. (US 20020012611).

Nakano discloses an apparatus comprising a dispensing mechanism, a moving mechanism, a microplate, reagent vessels and dispensing tip containers – see the appropriate paragraphs of the 07/13/2005 Office Action.

Nakano does not teach a first and a second reagent vessels to comprise pluralities of wells 'oriented in the Y-axis and X-axis directions correspondingly. However, the vessels comprising arrays of wells are routinely used in the art as reagent or sample vessels.

For example, Overbeck discloses systems for making ordered arrays where a "deposit device ['dispensing mechanism ' – Ex.] is ...constructed and arranged to dip into a volume of fluid carried by a ...storage device..., preferably the storage device being a 96 well plate or a plate having a multiple of 96 wells..." (Col. 7, lines 15-20).

Lebl discloses a synthesizer comprising, as shown in Figure 1, an array of reagent bottles 56. "Such a configuration is conducive to multiple channel delivery of

reagents to a microtiter plate having either 96 wells, 384 wells, or more wells arranged in an array on a microtiter plate. In the illustrated embodiment, reagent dispenser head 60 includes an array of forty nozzles arranged on five cartridges 66 (FIG. 1), wherein each cartridge 66 includes eight downwardly directed nozzles (not shown in FIG. 1) arranged in a linear fashion. Such a multiple channel delivery allows the simultaneous delivery of five different reagents, for example A, C, G, and T bases and an activator into respective wells 41..."(see [0057]).

Stylli discloses a high throughput chemical screening apparatus having a linear reagent dispenser 940 (Figure 7). The traditional 96-well plates "can be used to store chemical solutions in master plates in a storage and retrieval module. The sample distribution module aspirates a predetermined volume of chemical solution from all the addressable chemical wells of a master plate. The sample distribution module then dispenses a predetermined volume of chemical solution into a pre-selected portion of the addressable wells of a 384 daughter plate (i.e. compression). This process can be repeated to construct replicate arrays on the same or different daughter plate" –(see [0087]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed the reagent vessels comprising pluralities of wells oriented in the Y-axis and X-axis directions, in the modified apparatus of Nakano, in order to provide simultaneous delivery of different reagents in any predetermined order. Although Nakano does teach a second dispensing tip container ("used-tip dispensing box 6), the reference does not specifically teach that the tips in the

box would be arranged as a matrix. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged the tips in this manner in the second dispensing tip container of the modified apparatus of Nakano, in order to provide more efficient re-usability of the tips.

5. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakano in view of Overbeck, Lebl or Stylli, and further in view of Marouiss (US 20010048899).

Nakano modified by Overbeck, Lebl or Stylli, does not teach dispensing array coupled to rotating mechanism. Marouiss discloses "dispense manifold 3902 ...rotatable about pivot 3916, so that the effective separation between dispense elements 3910 can be adjusted to match the actual separation between sample wells 3908 in sample holder 3906. Specifically, dispense manifold 3902 may be rotated relative to a sample holder...Rotation of the array of dispense elements relative to the sample holder effectively decreases the separations between dispense elements relative to the sample holder"(See [0218]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed rotated dispensing unit in the modified apparatus of Nakano, in order to provide precise dispensing of the liquids.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakano in view of Overbeck, Lebl or Stylli, and further in view of Hilson (US 20030032191).

Nakano modified by Overbeck, Lebl or Stylli, does not s teach a micro-plate liquid handling system comprising thermomixer and cooler. Hilson discloses a sample

processing apparatus comprising a liquid handling system mounted on the frame;
“processing of the samples may include mixing fluid reagents and wash solutions with the samples on the surface of the supports. Mixing may be accomplished mechanically by agitation such as that achieved by (i) gross mechanical motion of the support housing, for example, rocking, rotating, tilting, orbiting, etc., (ii) vortex mixing through the action of directional gas or fluid flow guided by directional nozzles, (iii) fluid motion through the action of recirculated fluid pumping, (iv) ultrasonically by bulk-material or surface acoustic waves, (v) locally induced bubble formation and deformation through the action of localized heating, (vi) providing constant or intermittent dispensing and removal of wash fluid, and so forth”(See [0091]). In [0072] Hilson also teaches heat exchangers and coolers employed for controlling the temperature conditions in the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed thermo-mixers and coolers in the apparatus of Nakano, in order to provide the necessary temperature control for the system.

Response to Arguments

7. Applicant's arguments dated 03/29/2006 have been fully considered but they are not persuasive and moot in view of new ground of rejection.

Applicant argues that there is no motivation to modify the apparatus of Nakano such as to include the first and second dispensing tip containers and first and second reagent vessels comprising a matrix of elements allowing to keep the tips and reagents

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in a classified manner. Examiner disagrees. As was previously discussed, Nakano teaches that "the invention is not limited to employing only reservoir 3 for keeping reagents, "but, reagents different from the reagent 51 in the reservoir 3 may be ...distributed in the wells 4a ['second reagent vessel' – Ex.]"(Col. 7, line 65; Col. 8, line 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed the reagent vessels comprising pluralities of wells oriented in the Y-axis and X-axis directions, in the modified apparatus of Nakano, in order to provide simultaneous delivery of different reagents in any predetermined order. Additionally, Nakano teaches a tip holding rack 2 ['first dispensing tip container'] where the tips are kept in organized manner, and a second micro-plate 5, capable of being used for the same purpose. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged the tips in this manner in the second dispensing tip container of the modified apparatus of Nakano, in order to provide more efficient re-usability of the tips.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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